Public and Patient Research Priorities for Orthostatic Hypotension

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Abstract

With a rapidly expanding older population and increased survival of older people with chronic disease we can expect to see increasing numbers of people with orthostatic hypotension (OH). Unfortunately the evidence-base for people with OH, with particular relevance to older people, has not kept up and has resulted in a real lack of progress and little good evidence. There are several areas of research that could potentially benefit patients but establishing which ones are priority areas requires Public & Patient Involvement (PPI). This process includes people/patients in the research team to maximise the relevance, success and translation of the research. This brief report describes the early involvement of older people in prioritising the research question, methods to improve adherence during a trial and the preferred methods to disseminate research output. The individuals’ priority was to research non-pharmacological treatment strategies and to improve the education of patients about their condition. Education was felt to be the best strategy to promote adherence during a trial, with change in symptoms and quality of life felt to be the most important outcome measures as opposed to blood pressure. This report offers guidance for academics that are undertaking OH-related research and how they can improve its relevance and increase its translation into clinical practice.
Introduction

Orthostatic hypotension (OH) is a common condition affecting 7% of community-dwelling older people and up to 70% of people in long-term care [1]. However, despite the high prevalence there is very little evidence base underpinning the pathophysiology, diagnosis, management and prognosis, with evidence being even more rare when specifically required for older people [2]. OH is an important area for research because it has a heavy symptomatic burden, is associated with falls, depression and cognitive impairment and is also associated with an increase in mortality [3 4].

In order to deliver high quality research it is now recognised that involvement of patients and the public should be a priority. Indeed, all UK National Institute for Health Research (NIHR) Research Programmes now encourage this because it is well established that Public and Patient Involvement (PPI) leads to better research, clearer outcomes and faster translation [5 6].

Given the lack of evidence for OH, there is a need to prioritise which areas of research require the most attention. PPI is the ideal method to establish the patient and public priorities but can also be used to promote adherence, retention, dissemination and select appropriate outcome measures and improve dissemination of results. This paper presents the involvement of older people with OH participating in the early phases of research planning.
Methods

PPI is not research, rather it is consultation/collaboration, as such there is no strict methodology, analysis or approvals process. However, here we describe the processes involved and the outcomes in the format typical of a research paper.

Patients were invited to become involved in the discussion about OH related research via an independent charity. Involve North East (InvolveNE), is based in North East of England and specialises in innovative methods to involve patients and public in all aspects of research and service commissioning and design [7]. Their population databases may offer broader and more diverse groups of people than would be gained from a hospital clinic or primary care, in particular, hard-to-reach groups.

Those invited to be involved were aged over 60 years, had a diagnosis of OH were able to hold the discussion in English and agreed to discussions being recorded and transcribed. Those who expressed an interest were invited either to a group meeting or to have an individual discussion.

A member of InvolveNE, experienced in qualitative interview skills, performed semi-structured interviews. No members of the research team were involved at this stage, thereby reducing bias. Broad topics of discussion, which were predefined by clinical academics, were:

- Research priorities for people with OH
• Using non-drug or pharmacological treatments for OH
• Strategies to improve adherence with treatments
• Outcome measures to assess effectiveness of treatments
• Including older people with OH on the research team

Results

Of 250 community groups that were contacted, seven responded and agreed to a visit from InvolveNE. One focus group of two people was performed and three individual interviews were conducted. One person declined to give their age, but confirmed that they were aged over 60 years; the remaining four were aged over 60 years with one male and four females. All had OH, were White British and resided in non-affluent inner city areas.

PRIORITY 1

Although all five individuals understood the importance of researching the pathophysiology, diagnostic methods and prognosis of OH, their principle research priority was for the treatment of OH. Interestingly, four of the five people expressed a preference for researching non-drug treatments for OH:

“treatment would be good but not more medication, I already take enough medication”

Given that non-drug treatments generally have poor adherence, the individuals were asked how this could be improved during the course of a clinical trial. The
overall consensus was that if a treatment worked then people would adhere to it, with one person giving a limit of 4 weeks to allow something chance to work.

PRIORITY 2
After gentle prompting, all five people said that understanding more about how treatments work would improve adherence, with two specifying that this explanation would be better from people with OH rather than clinicians, who in their experience spoke in medical jargon. A frustration at the lack of understanding of their condition and the complexity of the information given to them was a common theme. Individuals described the use of medical jargon by clinicians and felt that if information was provided by people who have OH, such as in the design of leaflets, then adherence would improve and frustrations decrease.

“Explaining it in plain English because sometimes you get stuff through the post and it’s got loads of long medical words and I don’t know what that means”

OUTCOME MEASURES
Four people thought a clinical trial should assess response to treatment by measuring symptoms and one specified ability to perform everyday activities. This is in contrast to usual practice where measures of blood pressure are standard [8].

PPI
All five individuals thought that involving people with OH in the research team would be highly beneficial.

“I think it's a good idea to have someone who fully understands what it's like on the team, I would trust them more”

DISSEMINATION

On discussing whether people would be interested in the results of research, all would like to be informed of the results. When asked how they think this could be done, two people specified receiving the results in a newsletter, however one said they would prefer something more social, like a coffee morning. Another suggested having an animation on the Internet and being kept informed throughout the trial, rather than just at the end.

Discussion

The discussions presented here highlight the research priorities for a group of patients with OH who would not normally be involved in the research process. Older people are often excluded from research as a result of co-morbidity, polypharmacy and possible misplaced judgements about vulnerability [9]. Studies involving older people may also face greater challenges with recruitment, retention and long-term follow-up when compared to trials involving only younger people [9].

PPI is the initial step in identifying the research priorities for older people with OH. The discussions presented here demonstrate that the greatest priority is an
effective treatment for the symptoms of OH with a preference for non-pharmacological intervention. This is an important message for academics involved in the research of OH. It is easy for academics to have a paternalistic attitude, investigating what we feel is most important, often following the structure of the archaic ‘surgical sieve’. However, this paternalism is not acceptable for publically funded research, rather the priorities should be established together, with patients and academics working together as a research team. This approach improves the quality of clinical research and its translation into clinical practise [10].

In general, non-drug treatments for chronic conditions have poor adherence and clinical experience shows that this is true for the treatment of OH [11]. The PPI presented here provides new insights into potential strategies to improve adherence to these treatments. An understanding of the treatment was felt to offer the most potential; provided it is explained in jargon-free language. Involving patients and the public in the design of and writing of an educational resource would be a useful way to address this and would improve the understanding of the proposed treatment.

The predominant outcome measures used in studies relating to OH are all based on absolute BP values. In only a small number of trials are symptoms or quality of life used as an outcome measure, and in those cases as a secondary measure. However, the patients involved in these discussions clearly prefer change in symptoms or functional ability as an outcome measure. There are very few OH-specific symptom and quality of life measures, with no validation studies for use
in older people [12 13]. This is urgently needed to advance the quality of outcome measures in OH-related trials.

It is important to recognise that PPI is not solely to improve recruitment and dissemination strategies. Patients or public representatives can be involved in all aspects of the research process including protocol design, analysis and participating on the project steering group. All individuals who contributed to the discussions presented here appreciated this and felt that such involvement would improve the quality of the research.

A sample size of five may be considered as very small for a research study, but it is worth bearing in mind that this is not a research study, rather a consultation exercise. However, it is important to recognise that the views expressed in this piece of PPI may not represent the views of all older people with OH. Notably, those involved in this discussion were all community-dwelling, white British and from inner city communities. As we do not have data concerning comorbidities, precise ages and underlying pathophysiology we are unable to claim that the views stated here can represent the OH population as a whole. Nevertheless, we are able to share our experiences of the PPI process with other clinicians and academics involved in the care of and research for older people.

An interesting finding from this study, for others considering undertaking PPI, is that the older people invited to partake were not keen on group meetings, preferring to have individual discussion. This is relevant for those who wish to involve hard-to-reach groups as it demonstrates that there are people willing to
become involved in research who do not feel comfortable in the typical patient group environment. This may help researchers when involving patients and the public in their research to consider how to work with and recruit beyond the typical expert patient.
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Involve North East


